K071266

510(K) SUMMARY
BOSTON XO_2 (hexafocon B) Rigid Gas Permeable Contact Lenses for Daily Wear

AUG 15 2007

1. Applicant's Name and Address

Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609

2. Contact Person

Debra Ketchum
Manager,Global Regulatory Affairs
Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609
(585) 338-8638
debra.ketchum@bausch.com

3. Identification of Device

Common Name:	contact lens-rigid gas permeable (hydrophobic)
Trade Name:	Boston XO_2 (hexafocon B) Daily Wear Contact Lens
Classification:	Class II ophthalmic (21CFR 886.5916)
Device classification:	Class II (21 CFR 886.5916)
Product Codes:	HQD, MUW

Predicate Devices:

The predicate device, Boston XO (hexafocon A) was selected to address material use and design (aspheric, bifocal, toric, irregular corneas, and orthkeratology).

The BOSTON XO_2 is substantially equivalent to the currently marketed BOSTON XO cleared in 510(k) Premarket Notification Nos. K000795 on May 26, 2006, K001960 on August 28, 2000, K053124 on January 30, 2006 and K011945 on September 12, 2001. The difference between the two devices is a change in the component ratios.

K000795, K001960, K043124 and K011945: Boston XO (hexafocon A)

510(k)	Clearance Date	Device Description
K000795	5/26/2000	Boston XO RGP Daily Wear Contact Lenses
K001960	8/28/2000	Boston XO RGP for Daily Wear Orthokeratology Contact Lenses
K053124	1/30/2006	Boston XO, Boston EO, Boston ES RGP Daily Wear Contact Lenses (Post Surgical)
K011945	9/12/2001	Boston RGP Contact Lenses wet shipped and stored in Boston Advance Comfort Formula Conditioning Solution up to 30 days.

4. Description of device

BOSTON XO_2 (hexafocon B) Rigid Gas Permeable Contact Lens material is a fluoro silicone acrylate copolymer rigid gas permeable contact lens material. The material is available in blue, ice blue, green, or violet, yellow and red tint. The lenses may contain an ultraviolet light absorber, Uvinul D-49 or MHB. The blue and ice blue tinted lenses contain the color additive D&C Green No. 6; the green tinted lenses contain the color additives D&C Green No. 6 and C.I. Solvent Yellow No. 18; the violet tinted lenses contain the color additive D&C Violet No. 2, the red tinted lenses contain the color additive D&C Red No. 17; and the yellow lenses contain the color additive C.I. Solvent Yellow No.18. All of those color additives are listed in the Code of Federal Regulations (21 CFR 74.3206).

5. Intended use

BOSTON XO_2 (hexafocon B) Gas Permeable Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism, and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes.

BOSTON XO_2 may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

BOSTON XO_2 is also indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 5.00 diopters in non-diseased eyes. Note: To maintain the orthokeratology effect of myopia reduction, lens wear must be continued on a prescribed wearing schedule.

6. Description of Safety and Substantial Equivalence

A series of non-clinical laboratory testing and clinical testing was performed to demonstrate the safety and effectiveness of the BOSTON XO_2 contact lens material. A summary of results from the non-clinical and clinical tests is provided below.

6.1. Lens Compatibility/Cycling Study

The compatibility of BOSTON XO_2 material with several GP contact lens care regimens was assessed in this study. A lens cycling study was completed with each contact lens care regimen. Initial and final data were compared. There were no significant changes to lens parameters after 30 complete cycles.

6.2. Determination of Total Extractables Substances (ISO 10340:1995(E))

Total Extractables testing was conducted on three lots of BOSTON XO_2. The total amount of material extracted from BOSTON XO_2 was less than that extracted from BOSTON XO, the predicate device.

6.3. Determination of Extractable Color Additives and UV Blockers in Boston XO_2 Material (ISO 10340:1995(E))

Determination of Extractable color additives and UV blockers testing was conducted on Boston XO_2 material. These results are similar to those obtained when extracting Boston XO, the predicate device.

6.4. Cytotoxicity Study Using The ISO Agar Overlay Method (ISO 10993-5)

This in-vitro assay demonstrated the biocompatibility of this material. The test sample is placed on an agar surface directly overlaying a growing L-929 cell monolayer to determine if the material induces a cytopathic effect. The material did not induce cytotoxicity.

6.5. ISO Ocular Irritation Study (ISO 10993-10)

USP 0.9% Sodium Chloride Injection and sesame oil extracts of the Boston XO_2 GP lens material was evaluated for the potential to produce an irritating effect on the ocular tissue of the rabbits. According to the criteria of the study protocol, the material is considered to be a non-irritant.

6.6. USP and ISO Systemic Toxicity Test (ISO 10993-11)

This study was designed to evaluate acute systemic toxicity of the BOSTON XO_2 material extract following a single intravenous or intraperitoneal injection into mice. All observations of the mice were normal. The test samples meet the test requirements.

6.7. Bioburden of Lenses and Stability of Bioburden of Lenses Over time: Evaluation of the BOSTON XO_2 material (ISO 11987:1997)

A 30-day shelf-life study for Boston XO_2 lenses stored in Boston Advance Comfort Formula Conditioning Solution and Boston SIMPLUS Multi-Action solution was conducted. The average bioburden levels for BOSTON XO_2 lenses stored in lens cases with Boston SIMPLUS Multi-Action Solution and Boston Advance Comfort Formula Conditioning Solution after 30 days were within the acceptable bioburden limit of < 100 cfu/lens.

7. Clinical data:

The clinical investigation was conducted in accordance with the United States FDA regulations (21 CFR Parts 50, 54, 56 and 812), ICH Good Clinical Practices, ISO 14155-2 and the Declaration of Helsinki.

The objective of this controlled, multi-center clinical study was to evaluate the safety and efficacy of the BOSTON XO_2 (hexafocon B) Gas Permeable (GP) contact lens compared to the BOSTON XO (hexafocon A) GP contact lens when worn by adapted GP contact lens wearers on a daily wear basis.

Safety Conclusions:

The use of the BOSTON XO_2 (hexafocon B) gas permeable contact lens was well tolerated. There were no adverse events related to the BOSTON XO_2 product.

The results of this evaluation demonstrated that treatment with the BOSTON XO_2 (hexafocon B) gas permeable contact lens is safe when used as directed.

Efficacy Conclusions:

The vision provided by the BOSTON XO_2 (hexafocon B) contact lens is the same as vision with the BOSTON XO (hexafocon A) contact lens. Other Symptoms/Complaint measures associated with lens tolerance (Comfort, End of Day Comfort, Burning/Stinging Upon Insertion, Irritation, Itching, Dryness, and Redness) ratings demonstrated that the BOSTON XO_2 lens was at least as good as the BOSTON XO, overall, and at all follow-up visits for these attributes.

Other symptoms/complaints measures associated with lens tolerance (Comfort, End of Day Comfort, Burning/Stinging Upon Insertion, Irritation, Itching, Dryness, and Redness) ratings demonstrated that the BOSTON XO_2 article was at least as good as the BOSTON XO, Overall, and at all follow-up visits for these attributes.

Discussion and Overall Conclusions:

The results of this study demonstrated that there were no major complications associated with the use of the BOSTON XO_2 (hexafocon B) GP contact lens. This was supported by the fact that there were no adverse events, no test eyes required medical treatment and there were no slit lamp findings greater than grade 2.

Vision measures were acceptable for the BOSTON XO_2 (hexafocon B) GP contact lenses and were generally similar to the BOSTON XO contact lens. Symptoms/Complaints for various performance attributes associated with lens tolerance were also similar.

Overall, the investigators were satisfied with the vision quality that their subjects were able to obtain, the clinical performance of the lens met their expectations, and their subjects were successful wearing the BOSTON XO_2 (hexafocon B) GP contact lenses.

8. Conclusions drawn from studies

Substantial Equivalence:

Information provided in this 510(k) establishes that the BOSTON XO_2 GP Contact Lens is equivalent in optical, chemical, and physical properties of the predicate device and does not raise any questions of safety and effectiveness. The clinical evaluation demonstrated safe and effective lens performance and equivalence with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2007

Bausch & Lomb, Inc.
c/o Debra Ketchum
Manager, Global Regulatory Affairs
1400 North Goodman Street
Rochester NY 14609-3547

Re: K071266
Trade/Device Name: Boston XO2 (hexafocon B) Daily Wear Gas Permeable Contact Lens
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lens
Regulatory Class: Class II
Product Code: HQD, MUW
Dated: July 19, 2007
Received: July 23, 2007

Dear Ms. Ketchum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

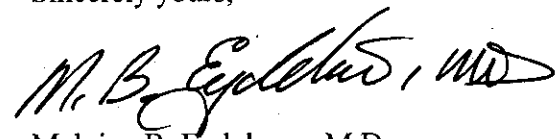
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071266

Device Name: Boston XO_2 (hexafocon B)

Indication for Use

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The lens may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g. LASIK) surgery.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the –counter-use_____

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K071266